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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	Criminal No. 17-320
	)	
v.	)	(18 U.S.C. §§ 371 and 1341 and 21 U.S.C. §§
	)	331(a), 333(a)(1) and 333(a)(2))
KEITH KOMAR	)	

INDICTMENT

FILED
NOV 29 2017
CLERK U.S. DISTRICT COURT
WEST. DIST. OF PENNSYLVANIA

The grand jury charges:

INTRODUCTION

At all material times:

1. The defendant, KEITH KOMAR, sold to consumers in the United States, through internet websites, prescription drugs, including prescription drugs manufactured and labeled for foreign markets. The internet websites included www.amerimexrx.biz, mymexmeds.com, and directconnectrx.com.

2. The defendant, KEITH KOMAR, caused an individual known to the grand jury then residing in India, to send prescription drugs manufactured in India directly to consumers in the United States, often through the United States mail, without obtaining a prescription for the drugs from the consumer.

FOOD, DRUG AND COSMETIC ACT

3. The Food and Drug Administration ("FDA") was the agency of the United States responsible for regulating the manufacture, labeling, and distribution of drugs in the United States. Among other things, the FDA was responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), including regulating the manufacture, labeling, and distribution of prescription drugs.

4. A "drug" was defined by the FDCA as, among other things, any article intended for

use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any such articles. 21 U.S.C. § 321(g)(1)(B)-(D).

5. A prescription drug was defined by the FDCA as "a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). A drug may also be limited to prescription use by its FDA-approved application. 21 U.S.C. § 353(b)(1)(B).

6. Before a new drug could be introduced in interstate commerce or marketed in the United States, it must have been the subject of an approved application filed with FDA, either for a pioneer drug or a generic version of the pioneer drug. 21 U.S.C. §§ 331(d), 355(a), (j). FDA approval was not only for the molecular entity itself (i.e. the active and inactive ingredients) but included the labeling.

7. The FDCA prohibited: (i) the introduction, and delivery for introduction and causing the introduction or delivery for introduction into interstate commerce of any drug that was misbranded, 21 U.S.C. § 331(a); and (ii) the receipt in interstate commerce of any misbranded drug, and the its proffered delivery for pay or otherwise, 21 U.S.C. § 331(c). Interstate commerce was defined in the FDCA as "commerce between and state or Territory and any place outside thereof." 21 U.S.C. § 321(b)(1).

8. A drug was misbranded if, among other things, its labeling lacked adequate directions for use. 21 U.S.C. § 352(f)(1). By regulation, the FDA defined "adequate directions for use" to mean "directions under which the layman can use a drug safely and for the purposes

for which it is intended." 21 C.F.R. § 201.5. Prescription drugs by definition could never contain adequate directions for lay use and were therefore misbranded unless they qualified for an exemption. By regulation, a prescription drug was exempt from Section 353(f)(1) if it met all enumerated conditions, including: (1) the drug was in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; (2) the label of the drug bore the statement "Rx only"; and (3) if the drug was a new drug, labeling in or within the package from which the drug was to be dispensed was the labeling authorized by the new drug application. 21 C.F.R. §201.100.

9. Prescription drugs could be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filled by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale. 21 U.S.C. § 353(b)(1)(B).

10. Bicalutamide is the active ingredient in a drug indicated for use in combination therapy with another drug to treat Stage 2 metastatic carcinoma of the prostate. It is a prescription drug that causes adverse reactions in over 10% of patients, and requires careful monitoring by a licensed medical practitioner to prevent liver damage, among other things. It is marketed in the United States under the trade name Casodex, manufactured by Astrazenaca Pharmaceuticals, and there are approximately 10 FDA-approved generic versions of this drug. The bicalutamide manufactured by Cipla Ltd is not approved for marketing in the United States.

11. Isotretinoin is the active ingredient in a prescription drug indicated to treat severe recalcitrant modular acne in patients 12 years old and older. It may only be administered in the United States to patients enrolled in a restrictive program with close patient monitoring by a medical professional. Isotretinoin labeling is required to carry a "black box warning", which is the strictest warning put on prescription drugs where there is evidence of a serious hazard associated with the product, in this case severe birth defects. Isotretinoin previously was marketed by Hoffman LaRouche under the brand name Accutane, though the manufacturer discontinued this product in 2009. Sun Pharmaceuticals currently has an approved new drug application for Isotretinoin sold under the trade name Absorbica, and there are also approximately five approved generic Isotretinoin drugs. The Isotretinoin drug manufactured by Indchemie Health Specialties PVT ltd, is not approved for marketing in the United States.

COUNT ONE – CONSPIRACY

12. The allegations set forth in paragraphs 1 through 11 are incorporated herein as if set forth in full.

13. From in and around a date uncertain in 2009, and continuing thereafter to in and around March 2016, in the Western District of Pennsylvania and elsewhere, the defendant, KEITH KOMAR, and other individuals and entities known and unknown to the grand jury (hereafter members of the conspiracy), engaged in a conspiracy to violate the following laws of the United States:

a. The introduction, delivery for introduction, or the causing of the introduction or delivery for introduction of misbranded prescription drugs with intent to defraud and mislead in violation of 21 U.S.C. §§ 331(a) and 333(a)(2);

b. Fraudulently and knowingly importing or bringing into the United States, any merchandise contrary to law, in violation of 18 U.S.C. § 545;

c. Facilitating the sale of any merchandise imported contrary to law, knowing the merchandise was imported contrary to law, in violation of 18 U.S.C. § 545; and

d. Mail Fraud, in violation of 18 U.S.C. § 1341.

MANNER AND MEANS OF THE CONSPIRACY

It was part of the conspiracy that:

14. The defendant, KEITH KOMAR, using various internet websites, advertised to customers in the United States the sale of unapproved prescription drugs that were manufactured for foreign markets and he made the following representations, among others, that, as the defendant, KEITH KOMAR, then well knew, were false, fraudulent, and misleading when made:

a. "We have been successfully operating this online pharmacy since 1995 providing high quality, safe, and approved medications meeting or exceeding the U.S. FDA standards";

b. "AmeriMex Rx represents the quality product line of Anand Medical who is a fully licensed pharmacy distributor serving 38 countries worldwide since 1995! Pharmacy license number: 20-Z7/97/162 Licensed pharmacist: Shailendra Sawant";

c. "Anand Medical is a FULLY LICENSED PHARMACY DISTRIBUTOR with several pharmacists on staff";

d. "Anand Medical exports products to over 5000 US pharmacies as well as pharmacies located in 38 countries worldwide. We sell a lot of the same medicine that is sold at U.S. pharmacies";

e. "ALL PRODUCTS SOLD ON THIS WEBSITE ARE APPROVED FOR

USE BY THE U.S. FDA.";

f. "Anand Medical strictly follows all rules and regulations set forth by the U.S. FDA."; and

g. "Anand Medical holds a NO OBJECTION CERTIFICATE issued by the Food and Drug Administration of India which means our packages pass through U.S. Customs without inspection."

15. The defendant, KEITH KOMAR, represented on his website that an individual known to the grand jury as JB was the President of Marketing, when in fact, as the defendant, KEITH KOMAR, then well knew, JB was one of KEITH KOMAR'S aunt's caregivers and had nothing to do with the business.

16. The defendant, KEITH KOMAR, represented on his website that an individual known to the grand jury as CC was the company's pharmacist, when in fact, as the defendant, KEITH KOMAR, then well knew, CC was a pharmacist that the defendant, KEITH KOMAR, met in Mexico and had nothing to do with the business.

17. The defendant, KEITH KOMAR, represented on his website that an individual known to the grand jury as MA was the Vice President of Sales, when in fact, as the defendant, KEITH KOMAR, then well knew, MA was the defendant KEITH KOMAR's son-in-law and had nothing to do with the business.

18. The defendant, KEITH KOMAR, represented on his website that he was a "licensed Pharmacy tech in Arizona", when in fact, as the defendant, KEITH KOMAR, then well knew, he was not a pharmacy technician.

19. The defendant, KEITH KOMAR, caused prescription drugs to be dispensed to consumers without requiring a prescription from a practitioner licensed by law to administer such

drugs, in that orders made over his website were shipped directly from defendant KEITH KOMAR's Indian suppliers to end-users in the United States.

20. Purchases made with credit cards on defendant KEITH KOMAR's website were directed through a payment processor, known to the grand jury, that did not identify defendant KEITH KOMAR or the true name of his business as the merchant, nor identify that the transactions were for prescription drugs, a practice for which credit card companies would not direct payments. The credit card processor would charge defendant KEITH KOMAR a fee for these services.

21. Members of the conspiracy arranged for the importation into the United States and the sale to consumers in the United States, including the Western District of Pennsylvania, misbranded prescription drugs. The prescription drugs were misbranded for, among others, the following reasons:

a. They were dispensed to consumers without a valid prescription from a practitioner licensed by law to administer such drugs, as required by 21 U.S.C. § 353(b)(1)(B)(iii); and

b. They did not contain labeling bearing adequate directions for use, as required by 21 U.S.C. § 353(f)(1).

22. Members of the conspiracy, including the defendant, KEITH KOMAR, caused payments for misbranded prescription drugs to be made from the Western District of Pennsylvania and elsewhere.

OVERT ACTS

23. In furtherance of the conspiracy, and to effect the objects of the conspiracy, the defendant, KEITH KOMAR, and other individuals known and unknown to the grand jury, did commit and cause to be committed, the following overt acts, among others, in the Western District

of Pennsylvania and elsewhere:

a. On or about November 19, 2015, a member of the conspiracy caused an entity associated with the conspiracy to send an e-mail to a purported customer referencing a purchase of thirty Accutane pills and thirty Casodex pills from www.amerimexrx.biz and also providing a statement that this purchase would appear on the credit card statements as "Paprika Shop +442820788444;"

b. On or about December 7, 2015, a member the conspiracy caused the delivery, sent through the United States Postal Service, of a package containing thirty tablets that contained Bicalutamide and thirty gelcaps that contained Isotretinoin;

c. In and around December 2015, a member of the conspiracy caused the customs declaration on the parcel referred to in the preceding paragraph to falsely report that the parcel contained a health product sample with no declared value;

d. On or about December 14, 2015, the defendant, KEITH KOMAR, sent an e-mail requesting that the recipient send payment for the products referring to in paragraph 23(b) to his address;

e. On or about January 14, 2016, the defendant, KEITH KOMAR, caused payment to be sent to his address for the purchase of thirty Celebrex pills, thirty Actos pills, and thirty Abilify pills ordered on the website www.mymexmeds.com without a prescription;

f. In and around January 2016, a member of the conspiracy caused the shipment of thirty pills labeled "Cobix-200 Celebixib," thirty pills labeled "Arpizol 10," and thirty pills labeled "Pioglit 30 Pioglitzone;"

g. In and around January 2016, a member of the conspiracy caused the customs declaration on the parcel referred to in the preceding paragraph to falsely report that the parcel contained a health product sample with no declared value.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO

The grand jury further charges:

24. The allegations set forth in paragraphs 1 through 11 and 14 through 23, are incorporated herein as if set forth in full.

25. On or about December 7, 2015, in the Western District of Pennsylvania and elsewhere, the defendant, KEITH KOMAR, introduced, delivered for introduction, and caused the introduction and delivery for introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead, namely 30 tablets containing Bicalutamide and 30 gelcaps containing Isotretinoin, that were misbranded in that:

a. They were dispensed to a consumer without a valid prescription from a practitioner licensed by law to administer such drugs, as required by 21 U.S.C. § 353(b)(1)(B)(iii);

b. They did not contain labeling bearing adequate directions for use, as required by 21 U.S.C. § 353(f)(1).

All in violation of Title 21, United States Code, Sections 331(a), and 333(a)(2).

COUNTS THREE AND FOUR

The grand jury further charges:

26. The allegations set forth in paragraphs 1 through 11 and 14 through 23, are incorporated herein as if set forth in full.

27. From in and around an uncertain date in 2009, and continuing thereafter to in and around March 2016, in the Western District of Pennsylvania and elsewhere, the defendant, KEITH KOMAR, and other individuals and entities known and unknown to the grand jury, devised and intended to devise a scheme and artifice to defraud and for obtaining money and property by means of false and fraudulent pretenses, representations and promises, well knowing at the time that the pretenses, representations and promises were false and fraudulent when made.

28. It was part of the scheme and artifice to defraud that the defendant, KEITH KOMAR, advertised the sale of prescription drugs through internet websites that contained false representations, including but not limited to the false representations referred to in paragraphs 14 - 19 of this indictment.

29. It was further a part of the scheme and artifice to defraud that, to the extent that the purchases were made using credit cards, participants in the scheme caused the concealment of the company name from the credit card companies in order to conceal the true nature of the transactions from the credit card companies.

THE MAILINGS

30. On or about the dates set forth below, in the Western District of Pennsylvania and elsewhere, the defendant, KEITH KOMAR, for the purpose of executing the aforesaid scheme and artifice to defraud, and in attempting to do so, did knowingly cause to be delivered by the United States mail, according to the directions thereon, the following matters:

Count	Date	Description
Three	December 7, 2015	EMS parcel EM823055928IN sent from Aman International, Mumbai, India (parts of the address stamp are unintelligible) to an address known to the grand jury in Pittsburgh, Pennsylvania containing 30 tablets containing Bicalutamide and 30 gelcaps containing Isotretinoin
Four	December 18, 2015	Postal money order No. 22896505416 in the amount of $230.00 sent from the Western District of Pennsylvania to AmeriMex International, LLC, 12661 E. Kalil Dr, Scottsdale, AZ 85259

In violation of Title18, United States Code, Section 1341.

A True Bill,

Foreperson

SOO C. SONG
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